K002752

NOV 2 0 2000

## Section 2 – Summary and Certification

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| **510(k) Summary of Safety and Effectiveness** | Information supporting claims of substantial equivalence under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements" (21CFR807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.<br><br>NEW DEVICE NAME: Bayonet Forceps Bipolar Irrigating<br><br>PREDICATE DEVICE NAME: Codman (J&J) Mirror Finish Bipolar Forceps Irrigitating Insulated |
| | 510(K) Summary |
| **Device Description** | The Q2 Medical Bayonet Forceps Bipolar Irrigating are a standard bayonet style forceps with a separate irrigation tube. They can be connected to the bipolar output mode on electrosurgical generators via either a standard bipolar cable or an irrigating tubing bipolar cable. |
| **Intended Use** | The Bayonet Forceps Bipolar Irrigating is intended for use in open surgical procedures wherever coagulation or cauterization of tissue to achieve hemostais is required. |
| **Indication Statement** | The Bayonet Forceps Bipolar Irrigating is intended to grasp and coagulate tissue. The irrigating tube facilitates local fluid irrigation through the forceps. The forceps can be used multiple times. |
| **Technological Characteristics** | The new device is technologically the same as the predicate |

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| **Performance Data** | Preclinical laboratory evaluations including compliance with AAMI/ HF-18 will be performed to ensure that the device functions as intended. Testing of the irrigation tube will also be conducted.<br>Clinical data were deemed unnecessary to support the Premarket Notification. Sufficient data have been gathered to assess the safety and effectiveness characteristics of the new device. |
| **Conclusions** | We conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act based on the similarity in intended use and function of the devices. |
| **Contact** | Mr. Mike Hand<br>Vice President, General Manager<br>Q2 Medical<br>3001 W. Kentucky<br>Louisville, KY 40211 |
| **Date** | August 30, 2000 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2000

Mr. Eric Mills, RAC
Senior Regulatory Affairs Specialist
Q2 Medical
c/o MedVenture Technology Corporation
2400 Crittendon Drive
Louisville, Kentucky 40217

Re: K002752
Trade Name: Bayonet Forceps Bipolar Irrigating
Regulatory Class: II
Product Code: GEI
Dated: August 30, 2000
Received: September 5, 2000

Dear Mr. Mills:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhorn

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002752

Device Name: Bayonet Forceps Bipolar Irrigating

Indication For Use:

The Bayonet Forceps Bipolar Irrigating is intended to grasp and coagulate tissue. The irrigating tube facilitates local fluid irrigation through the forceps. The forceps can be used multiple times.

(PLEASE DO NOT WRITE BELOW THIS LNE - CONTINUE ON ANOTHER PAGE IF NECESSAY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use____

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002752

(Optional Format 1-2-96)